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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/021,692      | 12/12/2001  | James E. Kipp        | IDD 5657 CIP3       | 9772             |

7590                    03/28/2003

MARK J. BUONAIUTO, ESQ.  
BAXTER INTERNATIONAL INC.  
LAW DEPARTMENT  
ONE BAXTER PARKWAY, DF2-2E  
DEERFIELD, IL 60015

[REDACTED] EXAMINER

OH, SIMON J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615     | 13           |

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                         |                  |
|------------------------------|-------------------------|------------------|
| <b>Office Action Summary</b> | Application No.         | Applicant(s)     |
|                              | 10/021,692              | KIPP ET AL.      |
|                              | Examiner<br>Simon J. Oh | Art Unit<br>1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-128 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-128 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-66 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-59, 110-115, and 119 of copending Application No. 09/953,979. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Claims 1-66 in the instant application are word-for-word duplicate claims or substantial duplicate claims corresponding to Claims 1-59, 110-115, and 119 in Application Serial No. 09/953,979.

Claims 67-97 are provisionally rejected under the judicially created doctrine of double patenting over Claims 1-120 of co-pending Application No. 09/953,979. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the rejected claims ultimately depend on independent Claim 66, which is a duplicate claim of Claim 119 in Application No. 09/953,979. The rejected claims are further limitations in the instantly claimed method, which substantially correspond to similar limitations found in the claims of Application No. 09/953,979 for similar processes. These similar claim limitations correspond to further modifying the independent base claim, in this case, Claim 66, by the addition of one or more surface modifiers to either the first or second solvent in the claimed method. Other claim limitations included in this provisional double patenting rejection include listing types of surface modifiers, such as anionic surfactants, cationic surfactants, nonionic surfactants, biological surface-active molecules, and phospholipids. Still other claim limitations in this rejection are drawn to naming specific solvents or surface modifiers, or listing surface modifiers as part of a broader group, such as anionic surfactants, cationic surfactants, nonionic surfactants, and phospholipids. Such claim limitations are substantially similar in structure to those that add further limitations on independent claims found in co-pending Application No. 09/953,979.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending

application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 12, 21, 30, 35, 47, 57, 72, 98, and 127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 6, 21, 30, 35, 47, and 57, the phrase “or other proteins” renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by “or other proteins”), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05.

Claims 12 and 72 contain the limitation “bile salt or salt thereof”. This limitation is unclear.

The wording of Claim 98, in section (iii), is unclear.

In Claim 127, it is unclear what is meant by the limitations, “essentially free” and “unspecified polymorphic form”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10, 11, 17-20, 25-29, 31-34, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Stainmesse *et al.* (U.S. Patent No. 5,133,908)

The Stainmesse *et al.* patent teaches methods of producing nanoparticles comprising first, preparing a liquid phase consisting essentially of a solution of the substance in a solvent or in a mixture of solvents to which may be added one or more surfactants; second, preparing a second liquid phase consisting essentially of a non-solvent or a mixture of non-solvents for the substance and to which may be added one or more surfactants, the non-solvent or the mixture of non-solvents for the substance being miscible in all proportions with the solvent or the mixture of solvents for the substance; third, adding one of the liquid phases prepared in first or second step to the other with moderate stirring so as to produce a colloidal suspension of nanoparticles of the substance; and fourth, if desired, the removal of all or part of the solvent or the mixture of solvents for the substance and of the non-solvent or the mixture of non-solvents for the substance so as to produce a colloidal suspension of nanoparticles of the desired concentration or to produce a powder of nanoparticles (See Abstract; Column 2, Lines 32-52; and Claim 1). Various organic compounds may serve as the substance in the disclosed process, including polymers, waxes, biologically active substances, or pigments (See Column 2, Line 60 to Column 3, Line 38). Solvents may be selected among various organic solvents, including methanol, ethanol, isopropanol, and acetone (See Column 3, Lines 46-68). Ethanol and distilled water are mentioned as examples of non-solvents (See Column 4, Lines 1-14). Surfactants suitable for use in the disclosed process includes anionic surfactants, such as sodium lauryl sulfate; cationic

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surfactants, such as quaternary ammonium; and non-ionic surfactants, such as ethers formed between fatty alcohols, and polyoxyethylene glycols (See Column 4, Lines 15-23). The disclosed process can produce nanoparticles smaller than 500 nm (Column 4, Lines 55-58).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-20, 22-29, 31-34, 36-46, 48-56, 58, 59, and 66-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.*

The relevant portions of Stainmesse *et al.* are detailed in the above rejection of Claims 1-5, 10, 11, 17-20, 25-29, 31-34, and 39 under 35 U.S.C. 102(b).

It is the position of the examiner that Claims 1-5, 7-20, 22-29, 31-34, 36-46, 48-56, 58, and 59 cannot be considered patentable over the disclosure of Stainmesse *et al.*

Claims 40-46 and 50-56 are directed to the use of phospholipids in the instantly claimed process. However, it is the position of the examiner that the limitations of these claims would be known to one of ordinary skill in the art, in light of what examiner believes to be a reasonably broad interpretation of the disclosure of Stainmesse *et al.* regarding the broad range of choice given to the selection of surfactants (See Column 4, Lines 4-16).

Claims 7-9, 12, 13, 22-24, 36-38, 48, 49, 58, and 59 are directed to the selection of particular solvents and surfactants for use in the applicant's claimed invention. It is the position

of the examiner that the applicant has not established a patentably critical distinction of the choice of these particular components over the disclosure of the prior art.

Claims 14-16 are directed to the use of pH adjusting agents in the instantly claimed process. However, it is the position of the examiner that the limitations of these claims would be obvious to one of ordinary skill in the art, in light of the disclosure of Stainmesse *et al.* regarding the manipulation of pH in the disclosed process (See Column 4, Lines 35-42).

Claims 66-97 are directed to a method of preparing submicron-sized particled of an organic compound, a process that comprises defining a pre-suspension of particles in a friable form. However, no active method steps are disclosed which imparts friability, thereby failing to distinguish the claimed process from what has been disclosed by the prior art. Therefore, the claims are considered to be obvious in view of the prior art.

Claims 60-65 and 98-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Hanna *et al.* (U.S. Patent No. 6,063,138)

The relevant portions of Stainmesse *et al.* are detailed in the above rejection of Claims 1-5, 10, 11, 17-20, 25-29, 31-34, and 39 under 35 U.S.C. 102(b).

The Stainmesse *et al.* patent does not teach the use of seeds in the preparation of particles or of suspensions comprising such particles.

The Hanna *et al.* patent teaches methods for forming particles of a substance using a solvent/anti-solvent system (See Abstract; and Column 11, Lines 33-47). The designated anti-solvent may contain a seed to induce nucleation of the substance. This seed may be a

pharmaceutically acceptable carrier or a pharmaceutically active material (See Column 10, Line 54 to Column 11, Line 20).

It would be obvious to one of ordinary skill in the art to combine the teachings of Stainmesse *et al.* and Hanna *et al.* into the objects of the instantly claimed invention. One of ordinary skill would be motivated to modify the disclosure of Stainmesse *et al.* in view of Hanna *et al.* in order to gain greater control of product characteristics, including size, size distribution, shape, and morphology. Hanna *et al.* also disclose that other factors may be manipulated for control of product characteristics, such as process flow rates, process temperatures, and process pressures (See Hanna *et al.*, Column 11, Lines 21-32). Claims containing limitations drawn to the selection of a particular drug, or drawn to steps of adding energy in various forms at various steps of the claimed process are not considered to be patentable in view of the prior art, absent a showing by the applicant demonstrating criticality or of results that would be unexpected by one of ordinary skill in the art at the time the claimed invention was made. Thus, the instantly claimed invention is *prima facie* obvious.

#### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo  
March 24, 2003

THURMAN R. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
